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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/202,181	12/10/98	REISNER	Y REISNER=5

001444 HM22/0921
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EXAMINER	
ZEMAN,R	
ART UNIT	**PAPER NUMBER**
1645	11

DATE MAILED: 09/21/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/202,181	Applicant(s) Reisner et al.
	Examiner Robert A. Zeman	Group Art Unit 1645

☒ Responsive to communication(s) filed on *Jul 12, 2000* .

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *5-12, 15-17, and 19* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☒ Claim(s) *5-8 and 12* is/are allowed.

☒ Claim(s) *9, 11, 15, 16, and 19* is/are rejected.

☒ Claim(s) *10 and 17* is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *8*

☒ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Response to Amendment

The amendment filed on 7-12-00 is acknowledged. Claims 1-4, 13-14 and 18 have been canceled. Claims 5, 9-12, 15 and 17 have been amended. Claim 19 has been added. Claims 5-12, 15-17 and 19 are pending and currently under examination.

Objections to Specification Withdrawn

The objection to the specification due to the unreadable on pages 4 and 10 is withdrawn in light of the amendment thereto.

The objection to the specification for the use of the abbreviations "Ad antigen", "HB" and "o.n." is withdrawn in light of the amendment thereto and Applicant's arguments which were found to be persuasive.

The objection to the specification due to non-compliance to the sequence rules set forth in 37 C.F.R. 1.821(a)(1) and (a)(2) is withdrawn in light of the amendment thereto.

Claim Rejections Withdrawn

The rejection of claims 5-12, 15-17 and 19 under 35 U.S.C. 112, first paragraph, for containing subject matter which was not described in the specification in such a way to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make

and/or use the invention is withdrawn in light of Applicant's executed Declaration of Biological Material Deposit.

The rejection of claims 1 and 12 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention through the use of improper punctuation is withdrawn in light of the amendment thereto. The cancellation of claim 1 renders the rejection moot.

The rejection of claim 4 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention through the use of trademark/ trade name is withdrawn. The cancellation of claim 4 renders the rejection moot.

The rejection of claims 5 and 6 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention through the recitation of improper Markush language is withdrawn in light of the amendment thereto.

The rejection of claim 5 and 6 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention through the use of the term "substantially" is withdrawn in light of the amendment thereto.

The rejection of claims 10-11 and 13-14 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention through the use of the terms "according to claim 5" and "in accordance with claim 5" is withdrawn in light of the amendment thereto. Cancellation of claims 13 and 14 render the rejection to said claims moot.

The rejection of claims 10 and 17 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention through the use the term "therapeutically effective amount" is withdrawn in light of the amendment thereto and Applicant's arguments which were found to be persuasive.

The rejection of claim 12 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention through the use of the phrase "antibody of any of Claim 5" is withdrawn in light of the amendment thereto.

The rejection of claim 17 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention through the use of the phrase "composition according to any one of claims 9" is withdrawn in light of the amendment thereto.

The rejection of claims 13, 14 and 18 under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See

for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966) is withdrawn. Cancellation of claims 13, 14 and 18 renders said rejection moot.

The rejection of claims 1-4 under 35 U.S.C. 103(a) as being unpatentable over Marcus et al. (Blood, Vol 86, No. 1 July 1, 1995 pages 398-406; IDS-2) in view of Ichimori et al. (Biochemical and Biophysical Research Communications. Vol. 142, No. 3. Feb. 13, 1987 pages 805-812; IDS-2) is withdrawn. Cancellation of claims 1-4 has rendered said rejection moot.

Claim Rejections Maintained

The rejection of claims 9, 11, 15-16 and 19 under 35 U.S.C. 112, first paragraph, because the specification, for being enabling for treatment of HBV infection, does not reasonably provide enablement for reducing the occurrence of HBV infections in a population of individuals (the prevention of HBV infection) is maintained for reasons of record. Applicant has substituted the phrase "reducing the occurrence of HBV infections in a population of individuals" for the term "prevention". The former phrase is a definition of the latter term. One cannot "reduce the occurrence of an infection in a population" without **preventing** said infection in individuals. Consequently, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The above rejected claims are drawn to prophylactic antibody vaccine compositions. To be a prophylactic vaccine, the vaccine must provide protective immunity,

demonstrable by viral challenge experiments, in a reasonable model system. The specification, as filed, does not set forth that the claimed composition provides any sort of protective immunity in any model system which can be extrapolated to humans or higher mammals. Applicant describes a "combined prophylaxis/inhibition mode" wherein a mouse was treated with antibody 19.79.5 before transplantation of human liver fragments infected with HBV *ex vivo* in the presence of antibody 19.79.5. Applicant further discloses that there was merely a reduction in the number of infected animals (see page 35, second paragraph) but does not disclose the duration, if any, of the effect of said antibody treatment. Additionally, Applicant describes a "combined inhibition/treatment mode" wherein HBV positive human serum was preincubated with antibody 19.79.5 followed by *ex vivo* liver infection; mice were treated with antibody 19.79.5 at days 0 and 7 post transplantation. Again, no protective immunity was demonstrated as there was merely a reduction in the number of infected animals not a prevention of HBV infection. Moreover, Applicant discloses that reduction in the number of infected animals was dependent on continued antibody treatment since all animals became infected two weeks after the cessation of antibody treatment (see page ~~35~~ 16, lines 16-18). While the skill in the art of virology is high, to date, prediction of protective immunity for any given composition is quite unpredictable. Given the lack of success in the art, the lack of working examples, and the unpredictability of the generation of protective immunity, the specification, as filed, is not enabling for such vaccines.

Conclusion

Claims 5-8 and 12 are allowed; claims 10 and 17 are objected to as depending from a rejected claim.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991. The examiner can be reached between the hours of 7:30 am and 4:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, Donna Wortman, Primary Examiner can be reached at (703) 308-1032 or the examiner's supervisor, Lynette Smith, can be reached at (703)308-3909.

DONNA WORTMAN
PRIMARY EXAMINER

Robert A. Zeman

September 19, 2000